Applicant: Barry O'Brien et al. Attorney's Docket No.: 10527-462001 / 02-253

Serial No.: 10/664,679

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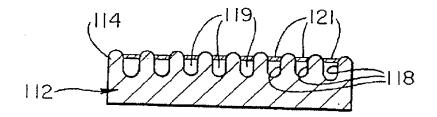
is the area within each tubular "hollow post-shaped element" (e.g., the area labeled as 27 in Fig. 2B).

The Examiner, however, asserts that:

Buscemi discloses a stent device having . . . a tubular member which includes a porous structure (fig. 6, lines 27-30), where the porous structure [is] defined by a plurality of hollow post shaped elements at 118, wherein the hollow post shaped elements separated by a void region at 105 and each hollow post shaped element defines an internal volume at 119 which [is] adapted to contain a therapeutic agent (see col. 11, lines 34-37).

(Office Action, page 2). The Examiner's characterization of Buscemi is completely without support. There is no disclosure in Buscemi that suggests that the porous structure is defined by the claimed hollow post-shaped elements. The Examiner's allegation that ref. no. 118 of Fig. 8 of Buscemi constitutes the claimed "plurality of hollow post-shaped elements" with the claimed "void region therebetween" is incorrect. Fig. 8 of Buscemi, reproduced below, "is an enlarged cross-sectional view of an outer surface of one embodiment of the biodegradable coiled stent." (Buscemi, col. 4, lines 2-4).





The only statement in Buscemi regarding ref. no. 118, is the following:

In one embodiment, the outer surface 114 is irregular and delineates pores 118, such as are illustrated in FIG. 8. The irregular outer surface 114 is a consequence of the conformation of the quasi-crystalline structure of the matrix 101 used to make the outer portion 112. In one embodiment, the pores 118 are filled with a gel 119, made of collagen, such as is illustrated in FIG. 8.

(Buscemi, col. 11, lines 33 - 42). This does not disclose, or even suggest, that the structures making up pores 118 constitute the claimed "plurality of hollow post-shaped elements separated

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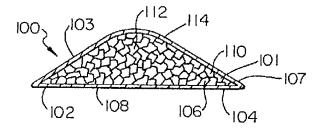
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by a void region therebetween." Accordingly, the rejection is improper and should be withdrawn.

The Examiner's allegation that ref. no. 105 of Buscemi identifies a void region between the claimed "hollow post-shaped elements" is also incorrect. Although none of the figures of Buscemi includes ref. no. 105, the specification of Buscemi discloses the presence of a "matrix 101 made of collagen IV and laminin" that "is essentially saturated with drugs . . . included within the voids 105 within the quasi-crystalline membrane matrix 101." (Buscemi, col. 10, lines 41-55). This disclosure suggests that voids 105 are throughout the body of the stent, not between a plurality of hollow post-shaped elements. The matrix 101 is shown in Fig. 6 of Buscemi, reproduced below.

Fig.6



There is no suggestion that each void 105 within the matrix 101 is between and separates a plurality of hollow post-shaped elements. It is noted that the claim requires that "the plurality of hollow post-shaped elements [be] separated by a [singular] void region therebetween." Buscemi does not disclose or even suggest such a void region.

Yan also does not disclose a porous structure defined by a plurality of hollow post-shaped elements. Elements 76 of Yan are macrostructures that form the bands of a stent. They do not define a porous structure. Instead, the elements 76 of Yan are themselves porous.

Accordingly, the rejection of claims 1-5, 11, 12, 15-21, 24-28, 31, 49, 50, 55, and 56 is improper and should be withdrawn.

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Additionally, with regard to claims 6-10, 13-14, 22, 23, 29, 30, and 51-54, neither Buscemi nor Yan discloses, suggests, or renders obvious hollow post-shaped elements having the claimed dimensions or properties. As discussed above, neither reference even discloses the claimed "porous structure defined by a plurality of hollow post-shaped elements." Applicants object to the Examiner's assertion that the "general conditions of [the] claim[s] are disclosed in the prior art." Furthermore, Applicants object to the Examiner's rejection of claims without providing any reason for why one having ordinary skill in the art at the time of invention would have made the modification. A citation to *In re Aller*, 220 F.2d. 454 (C.C.P.A. 1995), is not a reason. "[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). Because the Examiner has not even provided a reason for why one having ordinary skill in the art would have made these modifications to the device of Buscemi, the rejection fails to present a *prima facie* case of obviousness. Accordingly, the rejection is in error and should be withdrawn.

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue, or comment does not signify agreement with or concession of that rejection, issue, or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

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Respectfully submitted,

Date: 2/11/08

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